

DOCKET NO.: DIBIS-0003US (Counsel Docket No. 10310)**PATENT****REMARKS**

Applicants thank the Examiner for discussing the claims and the Fluitt reference during the July 12, 2006 interview. Applicants acknowledge the receipt of Form PTOL-413.

Claims 69-100 are pending in the present application. Claims 77 and 93 have been canceled and claims 101-104 are new. Claims 69-70, 78-79, 82, 84-86, 94-95, 98 and 100 have been amended. The claim amendments and the new claims add no new matter.

Claims 69 and 85 have been amended to recite that the amplification products are measured using a mass spectrometer. Support can be found throughout the specification, for example, at pages 24-25. Claims 69 and 85 have also been amended to recite that the target sequence region generated by a primer pair falls within a single gene sequence of at least eight bioagents, that the database is stored on a computer-readable medium and that the database comprises molecular masses of the target sequence regions from at least eight known bioagents. Support for these amendments can be found throughout the specification, for example, at page 13, lines 4-13 and page 14 lines 16-33 for the target sequence region; at figure 14 and table 2 for the at least 8 bioagents and the database with data for at least eight bioagents, and at page 33 for the database on a computer readable medium. Support for the amendment from bacterial bioagent to bioagent can be found, for example, on page 12. Claim 85 has also been amended to clarify that the number of each residue in an amplification product is calculated. Support for this amendment is found, for example, in Tables 1-7, figure 4 and pages 19-21. Other amendments to claims 69 and 85 were made to keep the claims terms consistent. Dependent claims 70, 78, 79, 82, 84, 86, 94-95, 98 and 100 have been amended for the purpose of maintaining antecedent basis with respect to the above-described amendments. These amendments are fully supported by the specification and original claims. No new matter has been added.

Amendments to the specification are merely correcting word processing errors. No new matter is added. The Statement of Government Support was amended to reflect the corrected contract number. The paragraph on page 15 was amended to correct a symbol in the purine analog. The Sala *et al.* reference correctly reports that the symbol should be "beta." The paragraphs on page 29 were amended to correctly reference the tables being discussed. The first amended paragraph states that the table shows data for *Mycobacterium avium* and *Streptomyces sp* and this is the data of Table 5, not Table 4. Similarly, the second amended paragraph references *Clostridium botulinum*, which is in Table 6, not Table 5. The

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paragraph spanning pages 30 to 31 was amended to correctly state that the highlights are bold, as can be seen in Table 6. This paragraph was also amended to correctly state that the table showing further distinction of organisms via multiple primers is Table 7, not Table 6. Applicants respectfully request the entry of these amendments into the specification.

Claim Interpretation

The Office Action states that the term "molecular mass" is being broadly read to encompass any mode of determination of molecular mass including mass determinations by sizing on gel electrophoresis ... Applicants respectfully note that in claims 69 and 85 molecular mass is determined using a mass spectrometer. The Office Action further states that the term "database," is read broadly so that any collection of information would satisfy this term. Applicants respectfully note that in claims 69 and 85 the database is in a computer readable medium and comprises bioagent indexed molecular mass or base composition data for a target sequence region.

Claim Rejections

I. Rejections Under 35 USC § 102(b)

A. *Fluitt et al.* WO95/13396

Claims 69-74, 79, 80, 82-90, 95, 96, and 98-100 were rejected under 35 U.S.C. §102(b) as being anticipated by *Fluitt* WO95/13396. Claims 69 and 85 have been amended to recite that the molecular masses are determined using a mass spectrometer. *Fluitt* does not teach this element. Claim 85 also recites a base composition calculation element that *Fluitt* fails to teach. Claims 70-74, 79, 80, 82-84, 86-90, 95-96, and 98-100 are dependent claim 69 or claim 85, thereby incorporating all of the elements of these independent claims. Applicants submit that *Fluitt* does not teach all of the elements of the claims, and respectfully request that the Examiner remove this rejection.

II. Rejections Under 35 USC § 103(a)

A. *Fluitt et al.* WO95/13396 in view of *Iliff et al.* US Patent 6,475,143

Claims 75, 76, 91 and 92 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Fluitt* WO95/13396 in view of *Iliff* 6,475,143. Claims 75 and 76 depend from claim 69, thereby incorporating all of the elements of claim 69. Claims 91 and 92 depend from claim 85, thereby incorporating all of the elements of claim 85. *Fluitt* is relied on for measuring a plurality of molecular masses. However, *Fluitt* does not teach or suggest

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using a mass spectrometer for measuring molecular mass. Fluitt also fails to teach or suggest the base composition calculation recited in claim 85. Thus, Fluitt neither teaches nor suggests all of the elements of these claims. Iliff does not remedy this defect. Applicants submit that the combination of Fluitt and Iliff does not teach or suggest all of the elements of the claims, and thus does not render these claims obvious. Although Applicants believe that the rejection is improper, in order to advance prosecution of this case, Applicants hereby incorporate the enclosed declaration under 37 C.F.R. 1.132 by Dr. Steven Buchsbaum. In his declaration, Dr. Buchsbaum notes that there was neither motivation, suggestion or teaching in the prior art for combining broad range priming with molecular mass measurements, and further notes the unexpected success of the technology. It is respectfully requested that the Examiner remove this rejection.

B. Fluitt et al WO95/13396 in view of Muddiman et al. (Anal. Chem. (1996) 68:3705-3712)

Claims 77, 78, 93 and 94 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fluitt et al WO95/13396 in view of Muddiman et al (Anal. Chem (1996) 68:3705-3712). Claim 77 and claim 93 are canceled. Claim 78 depends from claim 69 and claim 94 depends from claim 85, thereby incorporating all of the elements of the independent claims. Fluitt is relied upon for measuring a plurality of molecular masses of an amplification product using gel electrophoresis obtained using a primer pair that will bind to more than 100 bioagents, sequencing and comparing the amplified products with a set of reference sequences generated using an automatic sequencer, and delivering the identity of a bacterium from a match of the single stranded DNA sequence patterns. Neither Fluitt, Muddiman, nor the combination thereof teach or suggest a database stored on a computer-readable medium comprising molecular masses or base compositions from the target sequence region of at least eight bioagents. Applicants submit that the combination of Fluitt and Muddiman does not make these claims obvious. Although Applicants believe that the rejection is improper, in order to advance prosecution of this case, Applicants hereby incorporate the enclosed declaration under 37 C.F.R. 1.132 by Dr. Steven Buchsbaum. In his declaration, Dr. Buchsbaum notes that there was neither motivation, suggestion or teaching in the prior art for combining broad range priming with molecular mass measurements, and further notes the unexpected success of the technology. Applicants respectfully requested that this rejection be removed.

C. Fluitt et al WO95/13396 in view of Lebedev et al (Genetic Analysis: Biomolecular

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Claims 81 and 97 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fluitt *et al* WO95/13396 in view of Lebedev *et al* (Genetic Analysis: Biomolecular Engineering (1996) 13:15-21). Fluitt is relied on for measuring a plurality of molecular masses. However, Fluitt does not teach using a mass spectrometer for measuring molecular mass. Neither is Fluitt teaching calculated base compositions. Thus, Fluitt does not teach all of the elements of these claims. Lebedev does not remedy this defect. Applicants submit that the combination of Fluitt and Lebedev does not teach all of the elements of the claims, and thus does not render these claims obvious. Although Applicants believe that the rejection is improper, in order to advance prosecution of this case, Applicants hereby incorporate the enclosed declaration under 37 C.F.R. 1.132 by Dr. Steven Buchsbaum. In his declaration, Dr. Buchsbaum notes that there was neither motivation, suggestion or teaching in the prior art for combining broad range priming with molecular mass measurements, and further notes the unexpected success of the technology. Applicants respectfully requested that the Examiner remove this rejection.

Obviousness-Type Double Patenting

Claims 69-100 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 59, 60, 62, 63, 66, 69-76 and 79-94 of Application 10/156,608. Claims 69-100 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-28 of application 10/660,997. A terminal disclaimer with regard to co-pending applications 10/156,608 and 10/660,997 is filed herewith.

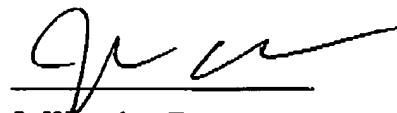
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In view of the foregoing, Applicants submit that the claims of the instant application are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there should be any questions with regard to the claimed invention.

Respectfully submitted,



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